

CAFFEMOL EFFERVESCENT TABLET

Paracetamol/Caffeine (500mg/65mg)

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What Caffemol is used for

Caffemol is used for the treatment of most painful and febrile conditions, for example, headache including migraine, backache, toothache, colds and influenza, sore throat, rheumatic pain and dysmenorrhoea.

How Caffemol works

The tablet contains 500mg Paracetamol and 65mg Caffeine. Paracetamol works by relieving pain.

The mechanism of analgesic action has not been fully determined. Paracetamol may act predominantly by inhibiting prostaglandin synthesis in the central nervous system (CNS) (specifically cyclooxygenase (COX)-2) and, to a lesser extent, through a peripheral action by blocking pain-impulse generation. Caffeine is a CNS stimulant. It stimulates all levels of the CNS, although its cortical effects are milder and of shorter duration than those of amphetamines.

Contact your doctor if you have any questions about the purpose of the Caffemol provided to you. Your doctor may prescribe for other purposes.

Before you use Caffemol

When you must not use it

Do not consume Caffemol if you have allergies towards:

- Paracetamol and any other ingredients listed at the end of this leaflet.
- Any other medicine which are similar

Do not consume Caffemol if you are taking other medicine that contains paracetamol.

If you experience any of the above conditions, consult your doctor or pharmacist.

Do not consume Caffemol after expiration date on this packaging or if there is a misuse of the packaging.

If the packaging is expired or damaged, return it to your pharmacy for disposal.

If you are not sure whether you should start taking this medicine, please consult your doctor.

Usage during pregnancy and breastfeeding:

Caffemol is not recommended for use during pregnancy due to the possible increased risk of lower birth weight and spontaneous abortion associated with caffeine consumption.

Caffeine in breast milk may potentially have a stimulating effect on breast fed infants.

Due to the caffeine content of this product, it should not be used if you are pregnant or breast feeding.

Before you start to use it

Please consult your doctor if you have any of the following:

- Allergy to any medicine, food, preservatives or coloring.
- Impairment of kidney or liver function.
- Addiction to alcohol.

If you are pregnant or breastfeeding, consult your doctor or pharmacist before consuming this medicine.

If you have high blood pressure, glaucoma, or overactive bladder syndrome.

If you haven't informed your doctor about any of the above, consult them before you start consuming Caffemol.

Care is advised in the administration of paracetamol to patients with renal or hepatic impairment. The hazard of overdose is greater in those with non-cirrhotic alcohol liver disease.

Taking other medicines

Tell your doctor or pharmacist if you are consuming other medication, such as warfarin and coumarins. Your doctor or pharmacist will have more information regarding medicines that are to be taken note of during the consumption of Caffemol or anything that should be avoided.

The speed of absorption of paracetamol may be increased by metoclopramide or domperidone and reduced by colestyramine.

The anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged regular daily use of paracetamol with increased risk of bleeding; occasional doses have no significant effect.

Caffeine may increase clearance of lithium. Concomitant use is therefore not recommended.

How to use Caffemol

Follow all instructions given by your doctor or pharmacist carefully. These instructions may differ from the information contained in this leaflet.

If you do not understand the instructions on this leaflet, consult your doctor or pharmacist.

How much to use

- Adults and children aged 16 years and over:

Take 2 tablets dissolved in at least half a tumbler of water every 4 hours as needed. Do not take more than 8 tablets in 24 hours.

- Children aged 12-15 years:

Take 1 tablet dissolved in at least half a tumbler of water every 4 hours as needed. Do not take more than 4 tablets in 24 hours.

- Not recommended for children under 12 years.

- Do not take more frequently than every 4 hours.

- Do not take longer than three days without consulting your doctor.

When to use it

Take your medicines as directed by your doctor.

How long to use it

Continue taking Caffemol as directed by your doctor. Please seek immediate medical advice if sickness lasts longer than 10 days, or if there is redness or fever lasting for more than 3 days.

If you forget to use it

Take the remaining dose as soon as you

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remember and then return to your usual recommended dosage. If the next dosage period is near, leave the forgotten dosage and take the next dosage on schedule as usual. Do not double the dosage to replace the forgotten dosage by taking more than one dosage at the same time. This may increase your chances of experiencing side effects. If you are not sure what to do, consult your doctor or pharmacist. If you have problems remembering when to take your medication, please seek advice from your pharmacist.

If you use too much (overdose)

The toxic symptoms of paracetamol overdose include vomiting, stomach aches, low blood pressure and sweating. More serious side effects include necrosis liver failure. Clinical and laboratory evidence for risk of liver failure may take up to 1 week to be detected. The main manifestations of liver failure are jaundice, hypoglycemia and metabolic acidosis which may take at least 3 days to develop.

If you or someone else may have taken an overdose of Caffemol, contact your doctor for advice or go to the nearest hospital emergency room immediately. This must be done without any sign of discomfort or poisoning. You may need medical attention immediately.

While you are using it

Things you must do

Always follow your doctor's instructions carefully. If you are about to start on any new medication, consult your doctor and pharmacist that you are taking Caffemol.

Consult with a doctor if your headaches become persistent.

Avoid other caffeine containing products. Too much caffeine may cause rapid heart rate, nervousness or sleeplessness.

Excessive intake of caffeine (e.g.: coffee, tea and some canned drinks) should be avoided while taking this product.

Things you must not do

Do not take more than the recommended dose unless advised by your doctor. Use the smallest effective dose. Taking more

than the maximum daily dose may cause severe or possibly fatal liver damage.

Do not take Caffemol to treat any other illness, unless instructed by your doctor. Do not prescribe the same dosage to others, even if they are experiencing similar symptoms.

Side effects

Adverse reactions of paracetamol-caffeine are rare when taken in recommended doses, but some undesirable effects such as skin rash or itching have been reported, sometimes with breathing problems or swelling of the lips, tongue, throat or face. Bruising or bleeding.

Adverse effect of Paracetamol: The side effects are rare and have been reported according to the body system; Thrombocytopenia and agranulocytosis (blood and lymphatic system disorders), anaphylaxis, cutaneous hypersensitivity reactions including skin rashes and angioedema (immune system disorders), bronchospasm (respiratory, thoracic and mediastinal disorders), hepatic dysfunction (hepatic effects).

Adverse effect of Caffeine: Nervousness and dizziness have been reported for the CNS.

When the recommended paracetamol-caffeine dosing regimen is combined with dietary caffeine intake, the resulting higher dose of caffeine may increase the potential for caffeine-related adverse effects such as insomnia, restlessness, anxiety, irritability, headaches, gastrointestinal disturbances and palpitations.

Tell your doctor if you observe anything that makes you feel unwell. Other side effects not listed above may occur in some patients.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and disposal of Caffemol

Storage

Keep your medicine in its package. If you take the medicine out of the

package, it may not be maintained in a good condition.

Store below 30°C. Keep it away from sunlight and moisture.

Keep the medicine in a place that is out of reach from children.

Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist on how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

White to almost white, round tablet, flat and plain on both sides. When dissolved in water, the tablet effervesces to produce a colorless solution with characteristic aroma.

- Ingredients

- Active ingredient

Each effervescent tablet contains:
Paracetamol 500mg
Caffeine 65mg

- Inactive ingredients

Sodium hydrogen carbonate, citric acid, mannitol, sodium carbonate, sodium benzoate, macrogol 6000, saccharin sodium, povidone K30, aspartame, coffee flavouring.

- MAL numbers: MAL25036031XC

Manufacturer

STELLAPHARM J.V. CO., LTD. – BRANCH 1

(A Joint Venture Company of Auxilto GmbH, Germany)

No. 40 Tu Do Avenue, Vietnam - Singapore Industrial Park, An Phu Ward, Thuan An Town, Binh Duong Province, Vietnam

Product Registration Holder

AUXI THERAPEUTICS SDN. BHD.

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